

prior to introduction into an animal, as recited in claim 25. Furthermore, Applicant submits that Schlameus neither discloses nor renders obvious introduction of a cell-polymeric composition into an animal and hardening a polymer in the composition to form a hydrogel following introduction into the animal, as recited in claim 27. Instead, Schlameus discloses an implant comprising a disc formed at least partially of microcapsules containing osteoprogenitor cells. These microcapsules range up to about 1mm in diameter (Table 1) and encapsulate the cells in a hydrogel matrix that is hardened *in vitro* during formation of the microcapsule (column 1, lines 32-36, see also U.S. Patent No. 4,391,909 to Lim). In contrast, the implants in one embodiment of the instant invention are formed as unitary constructs having an anatomic shape (see, *e.g.*, page 2, lines 23-28). Formation of exemplary hydrogels that are hardened after implantation are described in the specification on page 12, lines 9-13. Such uniform constructs are not contemplated by Schlameus, who instead discloses a suspension of microcapsules in agarose surrounded by an agarose donut (column 12, lines 35-45). Applicant submits that new claims 25-43 are patentable in view of Schlameus.

Rejections under 35 U.S.C. 103

The Examiner rejects claims 3, 5, and 23 under 35 U.S.C. 103 as being unpatentable over Schlameus in view of Barry, Dionne, and Bhatnagar. Applicant respectfully disagrees. Barry discloses a degradable hydrogel matrix designed to eventually “revert to the gel or solution state” (column 3, line 65) and be resorbed by the body. Dionne discloses an implantation vehicle containing cells in a hydrogel matrix core surrounded by a membrane that may be formed from the same hydrogel. Bhatnagar teaches use of a hydrogel having peptides attached. None of these references disclose or suggest an injectable cell-polymeric composition or a hardened cell-polymeric composition having an anatomic shape as recited in claim 25. All four references completely fail to disclose an implant having an anatomic shape. Barry teaches away from the invention by disclosing an implant that is designed to be resorbed without being replaced by endogenous tissue (column 3, lines 64-66); indeed, Barry’s implant is meant to prevent the formation of tissue, and the combination of his matrix with cells would thwart this purpose. As the Examiner notes, the core of the matrix disclosed by Dionne need not be hardened before implantation (page 18, lines 18-22); however, the exterior must be a hardened hydrogel to form

an adequate membrane for the matrix and cells within (page 16, lines 14-22; page 18, lines 11-30, discussing the core). In contrast, claim 27 recites that no part of the cell-polymeric composition should be hardened prior to implantation. Bhatnagar does not teach use of a hydrogel without peptides. Applicant submits that Barry teaches away from combination with Schlameus and that the combination of Dionne and/or Bhatnagar with Schlameus neither results in the present invention nor renders it obvious. Applicant submits that claims 25-43 are patentable over Schlameus, Dionne, Barry, and Bhatnagar, either separately or in combination.

The Examiner rejects claims 9, 12, 19, and 21 under 35 U.S.C. 103 over Schlameus in view of Nevo, Vacanti A, and Vacanti B. Applicant respectfully disagrees. Applicant submits that Nevo neither discloses nor renders obvious forming an implant having an anatomic shape. Rather, the implant of Nevo is “pressed into the injured site, filling up smoothly the defect” (column 3, lines 60-61). Applicant respectfully submits that failure to form microcapsules does not render the anatomic shape recited in claim 27 obvious. In addition, the implants of Vacanti A and Vacanti B require formation of fibers (column 4, lines 56-59; Vacanti B (p.7, column 2, “branching fiber networks . . . satisfy these needs”) or a mesh (column 6, lines 47-50) to which the cells must be attached (column 10, lines 11-13). No such mesh or fibers are required to perform the instant invention. Vacanti B further teaches away from the invention by disclosing a solid polymer disk on which cells are seeded in a monolayer (p.7, column 2, “Polymer discs seeded with a monolayer of cells . . .”). Applicant submits that the combination of Schlameus with one or more of Nevo, Vacanti A, and Vacanti B does not result in the claimed invention. Applicant submits that claims 25-43 are patentable in view of these references, taken either separately or in combination.

Rejections under 35 U.S.C. 112

Claims 1-9, 11, 12, and 14-24 are rejected under 35 U.S.C. 112 as being indefinite. Applicant respectfully disagrees. Nevertheless, these claims have been cancelled and new claims 25-43 introduced. The new claims are supported by material throughout the specification, especially originally filed claims 1-18, page 2, lines 13-17 and 23-28, page 3, lines 32-33, and page 12, lines 9-13.

Petition Under 37 C.F.R. 1.182

Applicant has submitted a Petition under 37 C.F.R. 1.182 to change the name of inventor, Linda Griffith-Cima to Linda G. Griffith. A Declaration outlining the procedure by which the name change was effected was submitted as well. Copies of the Petition and Declaration are submitted herewith.

In light of the foregoing Amendment and Remarks, Applicant respectfully submits that the present case is in condition for allowance. A Notice to that effect is respectfully requested.

A check for \$834.00 for the fee under 37 CFR 1.16(c) for the new claims is submitted herewith. Please charge any fees associated with this filing, or apply any credits, to our Deposit Account No. 03-1721.

Respectfully submitted,



Valarie B. Rosen
Registration Number 45,698

Choate, Hall & Stewart
Exchange Place
53 State Street
Boston, MA 02109
(617) 248-5000
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner For Patents, Washington, D.C. 20231 on Feb 26, 2001

